Procedure

Department: HUMAN RESEARCH PROTECTIONS PROGRAM
Policy Number: V.A.2
Section: Records, Documentation, and Fees
Review Responsibility: HRPP Policy and Procedure Committee
Original Creation Date: September 15, 2000
Revision Dates: March 19, 2004; August 30, 2004; November 16, 2005; November 10, 2008; May 21, 2010; July 1, 2015; October 10, 2016

Subject: Procedure for Planning and Implementing IRB Committee Meeting Agendas

Procedure:
This procedure provides guidance on the purpose, development, and implementation of the Institutional Review Board (IRB) Committee meeting agendas.

I. IRB Committee Responsibilities.
   A. At a convened IRB Committee meeting, the following items will be placed on the agenda for review:
      1. New IRB Proposals Submitted for Review. All newly proposed research involving human participants, excluding those projects that meet one or more of the exemption categories as authorized in 45 CFR 46.101(b) and 21 CFR 56. 104(d) or one or more of the expedited categories as authorized in 45 CFR 46.110 (See HRPP Policy III.C and III.D);
      2. Continuing Review Applications. Continuing review of all human participants research at intervals appropriate to the degree of risk, but not less than once per year, excluding those projects that meet one or more of the exemption categories as authorized in 45 CFR 46.101(b) and 21 CFR 56. 104(d) or one or more of the expedited categories as authorized in 45 CFR 46.101(b) (8) or (9) (See HRPP Policy III.C, III.D, and III.K);
      3. Major Amendments. All major amendments to currently approved human participants research activities that materially affect an assessment of the risks and benefits of the study or substantially change the specific aims or design of the study (See HRPP Policy III.J); and
      4. Unanticipated Problems Involving Risk to Participants or Others. All unanticipated problems involving risks to participants or others (See HRPP Policy III.L).
      5. Expedited Review Determinations. When a determination regarding a review conducted utilizing expedited review procedures has been made, this must be documented on the agenda provided to the IRB Committee for the next possible convened meeting as authorized in 45 CFR 46.110.
         a) This documentation must include a citation to the specific permissible category or categories justifying the expedited review.
         b) This documentation advises all Committee members of research proposals that have been approved under the expedited review procedure.
      6. Notification of Approvals by Chair. Exempt new study approvals, amendments, continuing review, and adverse events meeting the criteria for expedited review, and study closures are placed on the next available agenda as a notification.
      7. Noncompliance. The HRPP reports promptly to the IRB
Committee members any serious or continuing noncompliance with the federal regulations or requirements of the IRB as an item on the next convened IRB Committee meeting agenda (See HRPP Policy II.C).

8. **Audits and Monitoring.** The results of any auditing or monitoring process by the HRPP are reported to the IRB Committee on the agenda of the next regularly scheduled meeting.

9. **Education.** As necessary, a member of the HRPP Team will provide relevant educational material for the agenda at least monthly for IRB Committee members.

### B. Agendas and review materials

Agendas and review materials will be distributed to Committee members electronically one week prior to the scheduled meeting allowing ample time for adequate review and preparation.

### C. Addendums and review materials

Addendums and review materials will be distributed electronically to Committee members in a timely manner that allows ample time for adequate review of the addendum item. Consideration of the complexity and the scope of the research will be given in determining the appropriate time required for adequate review. The Committee member will notify the RCA if additional time will be required to allow for prioritization and reassignment of the addendum item.

### II. HRPP Regulatory Compliance Analyst (RCA) Responsibilities.

- **A.** It is the responsibility of the RCA to place all scheduled items for Committee review on the next available agenda.
- **B.** The RCA will assure that all relevant sections appear on the agenda that will be discussed during the Committee meeting.
- **C.** It is the responsibility of the RCA to place all approvals that have occurred since the previous Committee meeting by expedited means and determinations of exempt status on the agenda for notification by the Chair to the Committee.
- **D.** When an addendum to a finalized agenda is warranted, the RCA will assure distribution of the information in a timely manner that allows ample time for adequate review of the addendum item. Consideration of the complexity and the scope of the research should be given in determining the appropriate time for adequate review.
- **E.** If a Committee member notifies the RCA that additional time will be required for an adequate review the RCA will evaluate the addendum item for prioritization and reassignment of the addendum item.

### References:

- 45 CFR 46.101
- 45 CFR 46.110
- 21 CFR 56.104
- [HRPP V.A - IRB Office Records](#)